Remarks

Claims 27 and 35-43 are pending and under consideration in the current application. A Declaration under 37 CFR 1.132, of Dr. David Skoner, is included herewith.

Rejection under 35 U.S.C. §103

Claims 27 and 35-43 are rejected under 35 U.S.C. §103(a) as obvious and unpatentable over Sanchez, Hall and Annesi, in combination. Applicant respectfully traverses this rejection.

As acknowledged in the Office Action and stated in the article, Sanchez describes the use of glycophosphopeptical in the treatment of an infectious illness, asthmatic bronchitis. Asthamtic bronchitis is caused by viral infection.

Hall is apparently cited for teaching that there is "confusion" about the nature of asthma. Hall describes the etiology of bronchiolitis, a term used interchangeably with asthmatic bronchitis, and again, of viral origin. The Hall paper explores the relationship between bronchiolits and subsequent development of asthma in children, and says nothing about use of glycophosphopeptical. It is clear from the discussion in Hall, however, that asthma is considered a separate illness from bronchiolitis.

Annesi is apparently cited for teaching that there are no standard definitions, and no consensus on definitions, for asthma, sinusitis and rhinitis, and that there is no gold standard for diagnosing these conditions. The three references, in combination, are said to render the use of glycophosphopeptical obvious in the treatment of allergy and astham. Applicant respectfully disagrees with this assertion.

First, it should be pointed out that asthma is, in fact, well defined. As set forth in "Guidelines for Diagnosis and Management of Asthma", a publication of the NIH (referred to as "the Guidelines", copy enclosed), asthma is defined as "a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, in particular mast cells, eosinophils, T lymphocytes, neutrophils and epithelial cells". Asthma is an immune system – mediated disease, and studies of airway pathology show evidence of eosinophil and mononuclear cell migration into the lining

of the airways (Guidelines, page 8). In sum, asthma is not a viral disease, and there is no confusion about this is the scientific/health community.

Numerous assertions regarding upper and lower respiratory diseases appear in the first full paragraph on page 5 of the Office Action. It is asserted that there is no gold standard for the diagnosis of asthma, that upper and lower airway diseases coexist in many patients, that rhinitus is linked to extrinsic asthma and nonallergic rhinitus, and so forth. Applicants request clarification as to how any of these statements are relevant to the case at hand. None of these statements establish or even suggest that asthma is a viral illness caused by the same virus known to induce bronchitis or bronchiolitis. For example, even if there is difficulty in diagnosis, a statement with which Applicant does not agree (see Guidelines at pages 14-20), this would not form a basis for prescribing a drug used in the treatment of a viral illness, for a non-viral illness.

It is true that some of the symptoms of asthma, such as wheezing, may overlap with other disease states, including bronchiolitis. However, many disease states are characterized by the presence of wheezing, including pulmonary embolism, cardiac failure, foreign body, central airway tumors, aspiration, Carcinoid syndrome, chondromalacia / polychondritis, Loeffler's syndrome, Bronchiectasis, Tropical eosinophilia, Hyperventilation syndrome, Laryngeal edema, vascular ring affecting trachea, Factitious (including psychophysiologic vocal cord adduction), α1-Antiprotease deficiency, Immobile cilia syndrome, Bronchopulmonary dyplasia, Bronchiolitis (including bronchiolitis obliterans) and croup (see the Mayo Internal Medicine Review Board reference, enclosed herewith). The notion that one skilled in the art would be motivated, or find it obvious, to use a treatment regimen designed for one of these diseases for any other disease characterized by wheezing, is not supported by any evidence in the record, cited by the Examiner or known to Applicant.

Finally, Applicant would like to point out that additional features of Claim 27 are not taught or suggested in the cited references. As amended, claim 27 recites "A method of treatment of allergy and asthma patients in need of such treatment, comprising administering a pharmaceutical composition consisting essentially of glycophosphopeptical *in multiple doses for a short term treatment period of 1-20 days to*

induce a remission of several months during which further treatment is not necessary". The specific treatment regimen set forth in Claim 27 is described no where in the references.

The Declaration of Dr. Skoner fully supports Applicant's position. Dr. Skoner is a highly respected expert in the field of pediatric asthma and allergy. It is his view that the use of glycophosphopeptical in the treatment of asthma or allergy is not obvious, in view of the references cited, or any other reference known to him. Applicant respectfully submits that Claim 27, and dependent claims 35-43, are not obvious and respectfully request withdrawal of the §103 rejection.

Conclusion

Applicant respectfully submits that all outstanding issues have been addressed, and that Claims 27 and 35-43 are in condition for allowance. Such action is respectfully requested at an early date.

Please be authorized to charge any fees and or credit any overpayments to deposit account 50-3325. The below-signed individual is an authorized user of said account

Respectfully submitted,

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